UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No. 06-11337 Hon. Patti B. Saris **LEAVE TO FILE GRANTED ON SEPTEMBER 23, 2009**
THIS DOCUMENT RELATES TO: *United States ex rel. Ven-A-Care of the Florida Keys, Inc.* v. *Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation* Civil Action No. 09-CV-10547 MDL Action No. 1456 *United States ex rel. Ven-A-Care of the Florida Keys, Inc.* v. *Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation* Civil Action No. 00-CV-10698 MDL Action No. 1456 *California ex rel. Ven-A-Care of the Florida Keys, Inc.* v. *Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation* Civil Action No. 03-CV-11226 MDL Action No. 1456	

REPLY IN SUPPORT OF MOTION FOR APPROVAL OF THE SETTLEMENT BETWEEN CALIFORNIA, FLORIDA, AND RELATOR VEN-A-CARE OF THE FLORIDA KEYS ON BEHALF OF ITSELF AND THE UNITED STATES AND SCHERING-PLOUGH, SCHERING, AND WARRICK

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INTRODUCTION

The United States Department of Justice ("DOJ") asserts that it alone possesses an "absolute veto" over the settlement reached between Schering/Warrick, the Relator, and California and Florida (the "Settling Parties"), and that, in the absence of its consent, this Court lacks jurisdiction to even review the proposed settlement. For its position on the consent issue, DOJ attempts to stretch decisions of the Fifth and Sixth Circuits beyond recognition. As discussed in the Settling Parties' Joint Memorandum in Support of the Settlement ("Joint Memorandum"), there is a split with the Ninth Circuit on the narrow issue of whether DOJ consent is required after the expiration of the "seal" period and a decision by DOJ not to intervene. For the reasons set forth below, the Ninth Circuit view is faithful to the plain meaning and context of the statute, and its approach to interpretation of the False Claims Act is consistent with a recent First Circuit decision.

While the parties are at odds over the consent issue, the Court need not resolve this aspect of their dispute. Even if DOJ is assumed to have authority to withhold consent to the proposed settlement, there is no support for DOJ's position that its authority is unfettered and unreviewable. Despite their differences on the consent issue, the Fifth, Sixth, and Ninth Circuits each engaged in a thorough review of the settlements before them and of the reasons provided by DOJ for its failure to consent to those settlements. There is no support in those cases for the remarkable jurisdictional position that "there is no settlement to review" here because DOJ has not consented to it. Moreover, while DOJ baldly asserts that its reasons for declining to consent are not subject to judicial review, DOJ offers no legal authority for its position, nor does it respond at all to the legal analysis in the Joint Memorandum of the presumption of judicial review that applies in the circumstances presented here.

Additionally, though it maintains its reasons for refusing consent are irrelevant, DOJ provides three reasons that it is withholding its consent to this settlement, none of which holds up to even minimal scrutiny. First, contrary to DOJ's assertions, the record evidence after nine years of this MDL proceeding is more than sufficient to support this settlement. Second, DOJ has had ample opportunity to investigate the "newly added" drugs and – before filing its opposition brief – had not ever requested additional information of any kind from the Relator or Schering/Warrick. And, third, the $55 million dollar settlement is eminently fair and reasonable for the reasons set forth below and in the Affidavit of Paul Charnetzki submitted herewith.

Likewise, the objections raised by the various objecting state and county entities (the "Objecting Parties"), which are prosecuting their own AWP cases, do not provide any obstacle to this Court's approving the settlement. In fact, the positions advanced by the Objecting Parties merely confirm the structural obstacles to settlement and finality described in the Affidavit of Beth Trent in support of the motion to approve the settlement agreement. Massachusetts, for example, takes the position that even if Schering/Warrick reached a settlement and obtained a release directly from the United States Government, such a release would not extinguish Massachusetts's claims for the federal share. That position, combined with DOJ's contention that its unwillingness to consent strips this Court of jurisdiction, dramatically highlights the "roadblock" to finality that the Settling Parties are attempting to surmount. Furthermore, DOJ's position, as set forth in its preliminary objections and now its opposition brief, is inherently contradictory: while it wants to rely on the states to recover rather than litigate directly with Schering/Warrick, it says Schering/Warrick are not entitled to achieve a settlement that is at least as broad as the claims that the states are bringing for the federal share. After so many years of

litigation on the same underlying conduct, an MDL court cannot be so severely constrained without undermining fundamental policies of fairness, efficiency, and judicial economy.

Notwithstanding the concerted effort of DOJ and the Objecting Parties, the Settling Parties are confident that a final resolution is achievable consistent with the federal False Claims Act, and that their proposed settlement is a fair and adequate vehicle to do so. As suggested in their Joint Memorandum, the Court should proceed in a sequential fashion. The Court first should determine, following the oral argument on September 25, that the consent provisions of the FCA do not deprive it of jurisdiction, that the proposed settlement is subject to review and consent by the Court, and that the reasons proffered by DOJ for declining to consent are also subject to judicial review. Then, the Court should determine that the terms of the proposed settlement are fair, adequate, and reasonable on the basis of the affidavits and supporting evidence filed by the Settling Parties. To the extent that DOJ submits any evidence raising a dispute as to the reasonableness of the settlement, the Court should schedule an evidentiary hearing to resolve that dispute. Finally, if the Court concludes that the settlement is reasonable and the Court is prepared to consent and enter the requested findings, the Court should provide DOJ with notice and an opportunity to consent as well. If DOJ declines, the Court should review the reasons for its refusal to consent, and determine that they are arbitrary, capricious, and otherwise not in accordance with law.

ARGUMENT

I. THE PROPOSED SETTLEMENT IS REVIEWABLE BY THIS COURT EVEN IN THE ABSENCE OF CONSENT BY THE UNITED STATES.

DOJ's position on consent rests on a fundamentally flawed reading of the False Claims Act. However, even assuming *arguendo* that the Court concludes that DOJ enjoys broader rights to control the litigation beyond the initial 60-day sealing period, at the very least (i) DOJ must

state its reasons for withholding its consent in writing; (ii) DOJ's reasons are reviewable by a court; and (iii) a court may ultimately approve the settlement if it finds that DOJ's stated reasons for withholding its consent are arbitrary, capricious, or contrary to law.

A. DOJ Consent is Not Required in a Non-Intervened False Claims Act Case.

Contrary to DOJ's assertion, neither the plain language of the consent provision nor any other provision of the federal False Claims Act ("FCA") confers on DOJ anything more than a right to intervene for "good cause" or a limited right to object to a settlement without intervening, in an action in which the federal government has declined to intervene at the outset.[1] The Fifth and Sixth Circuit opinions on which DOJ relies to argue to the contrary do not bind this court, nor should they be considered persuasive for the reasons detailed below.[2]

Both the Fifth and Sixth Circuit cases acknowledge that the government's right to veto a dismissal cannot be absolute. Rather, both courts recognize that such a reading of the statute, even as applied during the initial 60-day sealing period, leads inevitably to a constitutionally infirmed result. *United States* v. *Health Possibilities, PSC*, 207 F.3d 335, 343-44 (6th Cir. 2000) (stating that "separation of powers issues" might arise if court "construed the consent requirement to apply to involuntary dismissals"); *accord Searcy* v. *Philips Electronics N. Am. Corp.*, 117 F.3d 154, 158 (5th Cir. 1997). Thus, despite their statements to the contrary, even the Fifth and Sixth Circuit depart from the plain language of the statute to hold that the consent

[1] DOJ asserts that the Supreme Court has identified the government's veto right as one of the rights that DOJ enjoys after it declines to intervene in a *qui tam* action. (United States' Mem. in Supp. of its Opp'n to the Mot. to Approve the Proposed Settlement Between Schering-Plough Corp., Schering Corp., Warrick Pharmaceuticals Corp., California, Florida and Relator, Ven-A-Care of the Florida Keys 3 n.1 (the "DOJ Mem.") (citing *United States ex rel. Eisenstein* v. *City of New York*, __ U.S. __, 129 S. Ct. 2230 (2009)).) The Supreme Court's dictum, however, did not analyze this issue at all, let alone "lay it to rest." Moreover, as noted below, the Court in *Eisenstein* implicitly recognized that a FCA case can be dismissed over DOJ's objections. *See Eisenstein*, 129 S. Ct. at 2233 n.2; *see* discussion *infra* at note 8.

[2] In addition, while Judge Tauro followed the conclusion of the Fifth and Sixth Circuits, the court did so without engaging in any articulated analysis or interpretation of the statute. *United States ex rel. Globe Composite Solutions, Ltd.* v. *Solar Constr., Inc.* 528 F. Supp 2d 1, 3 (D. Mass. 2007).

provision only applies to *voluntary* dismissals. *Searcy*, 117 F.3d at 155 ("We find the last sentence of 31 U.S.C. § 3730(b)(1) unambiguous in its declaration that courts may not grant a *voluntary* dismissal in a False Claims Act suit unless the U.S. Attorney General consents to the dismissal." (emphasis added)); *see also Health Possibilities*, 207 F.3d at 339 ("We now join the Fifth Circuit . . . and hold that a relator may not seek *voluntary* dismissal of any qui tam action with-out the Attorney General's consent." (emphasis added)). In short, the plain language of the statute alone cannot compel the extreme position that DOJ urges upon this Court.

As the First Circuit very recently instructed in construing a different section of the False Claims Act, "'[t]he plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.'" *United States ex rel. Duxbury* v. *Ortho Biotech Prods., L.P.*, No. 08-1409, __ F.3d __, 2009 WL 2450716, at *7 (1st Cir. Aug. 12, 2009) (quoting *Robinson* v. *Shell Oil Co.*, 519 U.S. 337, 341 (1997)). Viewed through this lens, and following the First Circuit's instructions, it is clear that the "plain language" on which DOJ wants to rely is much more limited in scope than DOJ argues.

The consent language on which DOJ relies for its position is found in Subsection (b) of the statute, which governs the initial 60-day sealing period, and its applicability is limited to that period. The statute is arranged in subsections, organized sequentially, based on the typical life-cycle of a False Claims Act case. Subsection (b), which governs the initial 60-day period (or longer if extended by a court) following the filing of a case, provides for the case to remain under seal while DOJ decides whether or not to intervene. *See* 31 U.S.C. § 3730(b). During this initial period, "[t]he action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting." *Id.* § 3730(b)(1). After that,

where DOJ declines to intervene, Subsection (c) largely transfers control of the litigation to the *qui tam* relator and limits DOJ's rights to direct the litigation to (i) a right to intervene for "good cause" shown and take over the prosecution of the case and/or (ii) a limited right to object to any settlement that the relator might reach without intervening, but only to prevent the relator and defendant "from artificially structuring a settlement to deny the government its proper share of the settlement proceeds." *Id.* § 3730(c)(3); *see also United States ex rel. Killingsworth* v. *Northrop Corp.*, 25 F.3d 715, 724 (9th Cir. 1994) (analyzing the import of § 3730(d) when read in conjunction with § 3730(c)(3)). Accordingly, the structure of the statute does not permit reading any broad DOJ consent right to extend beyond the initial 60-day sealing period. *See, e.g.*, *Barnette* v. *Brook Road, Inc.*, 429 F. Supp. 2d 741, 748 (E.D. Va. 2006) (noting that plain meaning of subsection alone could not control interpretation of statutory provision because "had Congress intended § 1681m(h)(8) to apply to the entire section, the logical location for such provision would have been a new subsection (i), not the final paragraph of subsection (h).")

Moreover, reading the consent language to extend beyond the sealing period creates conflicts with other provisions of the statute. *See Neang Chea Taing* v. *Napolitano*, 567 F.3d 19, 27 (1st Cir. 2009) ("[It is a] cardinal rule that courts must strive to harmonize all the provisions of a statute to give them all force and effect." (internal quotation marks omitted)). Once the Government completes its investigation and, as in this case, declines to intervene, "the person bringing the action shall have the right to conduct the action." 31 U.S.C. § 3730(c)(3). That the power to "conduct" the action unavoidably includes the ability to settle the action is confirmed by the text of the statute itself, which provides that where the government has declined to intervene, "the person bringing the action *or settling the claim* shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages." *Id.* § 3730(d)(2).

Thus, reading the act as a whole contemplates the relator stepping into the lead role to "conduct" and potentially resolve the action through settlement, subject only to the limited rights expressly reserved to the government by the statute.

The legislative history likewise reinforces the interpretation that DOJ's right to consent to a settlement does not extend beyond the initial sealing period. As the First Circuit recently wrote, the FCA's *qui tam* provisions outlined in Section 3730, "supplement federal law enforcement resources by encouraging private citizens to uncover fraud on the government." *Duxbury*, 2009 WL 2450716, at *1 (quoting *United States ex rel. Rost* v. *Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007)). Congress's 1986 amendments were specially geared to "encourage more private enforcement suits." *Id.* at *12. As Congress has increased the financial incentives for relators to bring FCA cases, it has armed DOJ with a wider range of tools that it can use to manage FCA litigation.[3] Accordingly, there is no longer any basis to stretch the applicability of DOJ consent rights beyond the initial 60-day sealing period, and construing the statute in this way clearly creates a disincentive for relators to bring cases if, as here, they are told after years of litigation that for no good reason at all the government can block their settlement with defendants and that there is nothing even the court overseeing the litigation can do about it. *See In re Spookyworld, Inc.*, 346 F.3d 1, 7 (1st Cir. 2003) ("Analysis starts, as usual, with the statutory language, although bare words would not license a result 'demonstrably at odds' with legislative intent." (citation omitted)); *Killingsworth*, 25 F.3d at 722 (Congressional intent

[3] Historically, DOJ had not enjoyed the right to intervene, so withholding its consent to dismissal was the only means that it had to control a *qui tam* case. *See* Act of March 2, 1863, ch. 67, 12 Stat. 696. In 1943, however, DOJ was granted an initial 60-day period in which to review all *qui tam* cases and decide whether to intervene. *See* Pub. L. No. 78-213, ch. 377, 57 Stat. 608 (1943). Even more recently, in 1986, Congress granted DOJ (i) the right to seek a court-authorized extension of the initial 60-day sealing period and (ii) the right to intervene and take over the case for "good cause" at any point in the litigation. *See* S. Rep. 99-345, *23-26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5288-91. While it is true that the consent provision pre-dates the statutory amendments, the Fifth and Sixth Circuits failed to give meaning to Congress' decision to relocate the consent provision to a subsection of the statute governing the commencement of the action and the initial seal period. *See Duxbury*, 2009 WL 2450716, at *1.

manifested in 1986 amendments to FCA "is fundamentally inconsistent with the asserted 'absolute' right of the government to block a settlement and force a private party to continue litigation."). Contrary to DOJ's assertion and that of the Sixth Circuit, (DOJ Mem. 2 (quoting *Health Possibilities*, 207 F.3d at 340)), a veto power surviving beyond the initial determination of whether or not to intervene is not needed to protect the Government's and public's interest in *qui tam* litigation. Rather, Congress has ensured adequate protection of such interests by amending the FCA to allow DOJ to intervene at any later time in the proceedings for "good cause." *See Minotti* v. *Lensink*, 895 F.2d 100, 104 (2d Cir. 1990) (where DOJ declines to intervene "little rationale remains for requiring consent of the Attorney General before an action may be dismissed").

Requiring DOJ's consent to a settlement after that initial sealing period has expired and DOJ has declined to intervene also leads to practical and very real problems as many courts have recognized. As the Ninth Circuit noted, DOJ cannot force the parties to continue litigating by refusing its consent. If the parties simply abandon the litigation, the Court will find itself forced to dismiss the suit for failure to prosecute (a dismissal on the merits). *Killingsworth*, 25 F.3d at 723; *see also United States ex rel. Hullinger* v. *Hercules*, 80 F. Supp. 2d 1234, 1241 (D. Utah 1999) *questioned in footnote by Ridenour* v. *Kaiser-Hill Co.*, 397 F.3d 925, 931 n.8 (10th Cir. 2005). In *United States ex rel. Summit* v. *Michael Baker Corp.*, for example, DOJ's claim of an "absolute veto power" left the "case to sit and do nothing on th[e] Court's docket." *United States ex rel. Summit* v. *Michael Baker Corp.*, 40 F. Supp. 2d 722 (E.D. Va. 1999). Such an untenable outcome is quite possible here where the litigation has already aged fourteen years and threatens to continue without end absent a settlement of the federal-share claims.[4]

[4] The Fifth and Sixth Circuit cases on which DOJ relies do not account for these practical difficulties, but a trial court cannot afford to ignore them. *See* JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS § 4.07[B][2]

B. Even if DOJ's Consent Rights Extend Beyond the Seal Period, DOJ Does Not Enjoy an Unreviewable "Absolute Veto Right."

The Court need not agree that the consent provision is limited to the 60-day seal period to ultimately approve the settlement.[5] This is so because, even if DOJ is entitled to withhold consent, the Court must be able to evaluate DOJ's reasons for doing so. The Court itself raised this point at the hearing on July 24, 2009. (*See* 7/24/09 Hrg. Tr. 46:23-24 (discussing the applicable standard of review).) In response, DOJ now asserts that its "absolute veto" actually deprives the Court of jurisdiction to review either the settlement or the basis for DOJ's refusal to consent. (DOJ Mem. 2 ("[T]he Government's veto authority is absolute and not subject to judicial review . . . ."); *id.* at 5 ("Absent the Government's consent, there is no 'settlement' for the Court to consider . . . .").) DOJ's remarkable claim of such unfettered authority to obstruct the dismissal of a FCA action is not supported by a single citation to authority.[6] Nor does DOJ deign even to respond to the fact that the circuits addressing the consent issue each went on to review DOJ's stated justifications for refusing to consent. (*See* Joint Mem. 27.)

The analysis begins, as it should, with the statute. *In re Hill*, 562 F.3d 29, 32 (1st Cir. 2009). Section 3730(b)(1) of the FCA provides, in relevant part, that "[t]he action may be dismissed only if ***the court*** and the Attorney General give written consent to the dismissal and their reasons for consenting." *Id.* (emphasis added). Congress accordingly granted to "the

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(3d. ed. 2009) (questioning the rationale and conclusions reached in *Searcy* and *Health Possibilities* where the Fifth and Sixth Circuits fail "to explain the practical question of how a court or the government can force the parties to continue to litigate").

[5] However, it this Court concludes that the consent issue is dispositive, Schering/Warrick expect that they would request that the Court certify this controlling legal question for review by the First Circuit as an immediate appeal would materially advance the ultimate termination of this litigation. *See* 28 U.S.C. 1292(b).

[6] In fact, this Court already has denied DOJ's assertion of an unconditional authority to exercise its "consent" powers in the absolute. *See In re Pharmaceutical Industry Avg. Wholesale Price Litig.*, 538 F. Supp. 2d 392, 397-98 (D. Mass. 2008) (distinguishing *Health Possibilities* and *Searcy* to allow dismissal of claims in relator action over DOJ's "insist[ance] that the dismissal of the claim . . . was ineffective because the government never consented in writing").

court" the identical role that DOJ's untenable interpretation assigns to the Attorney General alone. Implicit in DOJ's position, therefore, is the proposition that Congress assigned an "absolute veto authority" to both the Attorney General and the court, and that the failure to consent by either the court or DOJ is insulated from judicial review. This position cannot be accurate as to the court, whose decisions are reviewable by an appellate court, and there is nothing in the quoted language of the statute that elevates the consent of the United States above that of the court. Thus, among other basic flaws, the Government's position violates established principles of statutory construction requiring the Court to adhere to the plain meaning of the statute and to avoid interpretations that render a provision superfluous or which lead to an absurd or incongruous result. *See United States* v. *Green*, 407 F.3d 434, 442 (1st Cir. 2005) ("Courts ought to construe statutes, whenever possible, in a commonsense manner, honoring plain meaning, and avoiding absurd or counter-intuitive results." (internal quotation marks omitted)); *Herman* v. *Hector I. Nieves Transport, Inc.*, 244 F.3d 32, 36 (1st Cir. 2001) ("A primary canon of statutory construction is that a statute should be construed so as not to render any of its phrases superfluous."). Moreover, DOJ's strained reading of the FCA, if adopted, would violate the constitutional principle of separation of powers by allowing DOJ to interfere in a core Article III function assigned to the court by the FCA.[7]

Notably, beyond its unsupported argument on jurisdiction, DOJ does not address the Settling Parties' arguments regarding this Court's exercise of judicial review. (Jt. Mem. 26-28.)

[7] Several Circuits have rejected similarly strained readings of the consent provision on this ground. *See Health Possibilities*, 207 F.3d at 344 (stating that "separation of powers issues" might arise if court "construed the consent requirement to apply to involuntary dismissals"); *Searcy*, 117 F.3d at 158 (same); *Killingsworth*, 25 F.3d at 722 & n.5 (consent provision "has limited application," and "government's consent to dismissal is not required . . . [for] court-ordered dismissals and involuntary dismissals"); *see also* Matthew H. Solomson & Sarah M. Brackney, *What Would Scalia Do?-A Textualist Approach to the Qui Tam Settlement Provision of the False Claims Act*, 36 Pub. Cont. L.J. 39, 49, 50-51, 52-53 (2006).

Absent a clear congressional mandate or a specific statutory provision stripping an Article III court of jurisdiction and review, courts are to proceed from the "'strong presumption that Congress intends judicial review,'" particularly when the determination to be reviewed is a matter of the Attorney General's exercise of statutory authority. *Gutierrez de Martinez* v. *Lamagno*, 515 U.S. 417, 424 (1995) (quoting *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986)). The Supreme Court has "stated time and again that judicial review of executive action 'will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress.'" *Id.* (quoting *Abbott Labs.* v. *Gardner*, 387 U.S. 136, 140 (1967)).

As discussed at length in their Joint Memorandum, each court addressing the scope of the consent provision, including the Fifth and Sixth Circuits, have recognized their role under the FCA and, accordingly, have exercised judicial review and scrutinized the reasons advanced by DOJ for objecting to a settlement. *See Health Possibilities*, 207 F.3d at 338, 341 (finding DOJ's objection that settlement "channeled damages payments" away from the government well-founded where settlement provided "no monetary recovery on the FCA claim"); *Searcy*, 117 F.3d at 158, 160 (determining that DOJ's objection to scope of release raised a "legitimate concern" where relator "bargained away" government's potential claims in the face of DOJ's minimal (120 day) investigation); *Killingsworth*, 25 F.3d at 725 (ruling that DOJ's objections "rest[ed] on good cause" where settlement allocated majority of damages to relator's personal claim). Although cited by DOJ for the proposition that it has an absolute right to veto a settlement reached by the relator at any point in a FCA case, the analyses in the Fifth and Sixth Circuit decisions show that the courts actually engage in the very type of review that DOJ argues here is inappropriate in order to confirm that DOJ had, at least, good cause to object to the

settlement in the circumstances of each case. *See Health Possibilities*, 207 F.3d at 338, 341 (questions of improper allocation); *Searcy*, 117 F.3d at 158, 160 (same). Here, nothing in the statute or its legislative history overcomes this presumption favoring judicial review.[8]

II. DOJ'S REASONS FOR REFUSING TO CONSENT TO THE SETTLEMENT ARE ARBITRARY, CAPRICIOUS, AND CONTRARY TO LAW AT BEST.

Perhaps recognizing that its "veto" arguments are legally unsustainable, DOJ's memorandum continues and, in completely cursory fashion, lists three reasons why DOJ says it is objecting to the proposed settlement. None of these purported reasons has any merit nor, as the discussion that follows demonstrates, is any one of them – either standing alone, or even taken collectively – sufficient to withstand judicial scrutiny.

A. Contrary to DOJ's Claims, There Is a Sufficient Evidentiary Basis for the Court to Make the Requested Factual Findings.

More than fourteen years after the commencement of this AWP litigation, DOJ asserts that it is withholding its consent to the Proposed Settlement because the Settling Parties have not provided the Court a sufficient evidentiary basis from which the Court can conclude that, throughout the relevant period, CMS (formerly HCFA) was aware that there is typically a 30% spread between a brand drug's AWP and the average selling price for that drug. (DOJ Mem. 8-9.)[9] DOJ makes this claim despite acknowledging in the very next sentence of its brief that "an extensive amount of discovery has been taken in connection with the three *qui tam* actions in which the United States has intervened" (*id.* at 9) – so much so, that DOJ has moved for the entry of summary judgment in its favor in the intervened cases. Although the relevance of the

[8] In addition, the Supreme Court in *Eisenstein* implicitly recognizes the reviewability of DOJ's refusal of consent. *See Eisenstein*, 129 S. Ct. at 2233 n.2 (noting that DOJ may appeal a non-intervened FCA action that has been dismissed over its objection). The converse must also hold true. A relator or settling party must have a right to judicial review and appeal in circumstances in which a FCA case is not dismissed as a result of a DOJ objection.

[9] As a related matter, it is worth noting that DOJ does not dispute any of the analysis or calculations set forth in Dr. Addanki's affidavit submitted in support of the Proposed Settlement.

AWP evidence amassed in those intervened cases might be disputed as it relates to the government's knowledge of the claimed "mega-spreads" (as DOJ's Memorandum suggests that it is (*see id.*)), the plain import of the evidence as it relates to this Court's analysis of liability for brand drugs with only modest and predictable spreads is clear. Based on the discovery record in the intervened cases, there can be no doubt, as this Court found in the MDL class case, that "government and industry were well aware by the late 1990's that there was a 20 to 25 percent spread" between published AWPs and WACs for brand drugs. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 32 (D. Mass. 2007) (this Court's "MDL Class Opinion") [Dkt. 5492]. Accordingly, DOJ's suggestion that, "[t]o the extent the Court must make any findings with regard to the federal or state governments' knowledge, consideration, or expectations, it should do so in the context of a fully developed factual record, not in the context of consenting to a proposed False Claims Act settlement," (*see* DOJ Mem. 9), at best places form over substance, and rests on a technicality that is easily cured.

As this Court has said on many prior occasions, "All the other depositions from the other cases [in this MDL] can be used" in any case in this MDL – "That's what we do in these multidistrict litigations." (2/12/09 Hrg. Tr. 23:17-20; *see also* 11/13/08 Hrg. Tr. 42:11-12 (remarking about the Rule 30(b)(6) deposition testimony of the states taken in the intervened cases, "[i]f it's out there under oath, it can be used" for purposes of summary judgment). If DOJ insists, the Settling Parties would be prepared, either at the September 25, 2009 hearing or at a subsequent hearing, to formally introduce all of the evidence amassed in the intervened cases and all of the evidence admitted in the MDL class case, including the testimony of Dr. Raymond Hartman, to cure any technical deficiency that DOJ might perceive.

The Settling Parties were, however, hopeful that they would not need to introduce or re-introduce this evidence in light of the United States' Statement Regarding the Court's Prior Rulings filed on August 7, 2008. As that filing recites, during a July 24, 2008 hearing on a discovery motion, this Court pressed DOJ to state whether "the government is contesting this Court's adoption of a spread threshold in determining liability and damages in other AWP fraud cases." (*See* United States' Statement Regarding the Court's Prior Rulings 1 [Dkt. No. 5492] (*citing* 491 F. Supp. 2d 20, 92 (D. Mass 2007) .) At the hearing, DOJ had been unable (or unwilling) to take a position.[10] In its subsequent filing, however, DOJ discusses at length its addition of a "formulaic spread of 25%" when deriving alternative AWPs and plainly states that "the United States's damages calculations take into account the typical differential between a manufacturer's reported prices and AWP." (*See* i*d*. at 2.) DOJ's *amicus* brief before the First Circuit filed in the AstraZeneca appeal takes a similar position. *See* Br. of the United States as Amicus Curiae in Partial Support of Plaintiffs-Appellees at 17, *Blue Cross Blue Shield of Mass.* v. *Astrazeneca Pharm. LP*, No. 08-1056 (1st Cir. Sept. 16, 2008). If these filings were intended to suggest anything other than that DOJ accepts this Court's MDL class case liability standards then, in Schering/Warrick's view, they are misleading. Furthermore, the Settling Parties fail to understand how these prior court filings can be reconciled with DOJ's current litigation position that the Proposed Settlement is somehow objectionable because of an insufficient factual record. Even so, if – in the end – DOJ chooses to stand on this objection, as noted above, this

[10] The following exchange from the July 24, 2008 hearing is telling:

> THE COURT: So are you willing to waive the first 30 percent?
>
> MR. GOBENA: I can't respond to that now. Certainly I'm willing to consult with other folks on my team.
>
> THE COURT: But let me be clear. Your knowledge, your briefing is inconsistent with what you're saying.

(7/24/08 Hrg. Tr. 7:22-8:4.)

technicality is easily remedied and should not be an impediment to the Court's consenting to the Proposed Settlement and entering the requested dismissal order.

B. DOJ's Objection to the Release of Certain Drugs Because They Were "Only Recently Added" and "Never Fully Investigated" Is Baseless.

DOJ also suggests that the Proposed Settlement should not be permitted to proceed because it would "result in the release with prejudice of the United States' claims in connection with drugs that were only recently added [to the Complaint] and which the Government did not fully investigate." (DOJ Mem. 10.) This objection, too, is baseless. As an initial matter, by the time of the September 25, 2009 hearing on this settlement, DOJ will have had notice of these precise claims for three months (since June 26, 2009, when the Proposed Settlement was made public on this Court's docket) and much longer than the 60 days typically afforded DOJ to review *qui tam* claims, and the 51 drugs about which DOJ complains will no longer be properly characterized as "only recently added." If the addition of these "new" drugs prompts DOJ to elect to intervene, the Court (and the Settling Parties) will know by then. Otherwise, they will know that DOJ does not intend to stand on this objection.

DOJ's assertion that it "never fully investigated" these drugs amounts to nothing more than an arbitrary (mis)characterization of its own creation. There is no dispute that both Schering/Warrick and the Relator have provided DOJ with absolutely every document, shred of evidence, and piece of data that DOJ has ever requested during the entire course of its eleven year investigation of Schering/Warrick's price reporting conduct. DOJ does not dispute that, in February 2008 (more than eighteen months ago), Schering/Warrick furnished DOJ with the very same "spread" and sales at WAC analysis that is set forth in Dr. Addanki's affidavit filed in support of the requested brand drug findings in this case. Nor, does DOJ mention (let alone dispute) that, when DOJ asked Schering/Warrick for information concerning Medicaid's

utilization of the "22 additional Warrick generic drugs" now at issue as a part of assessing a Schering/Warrick settlement offer in September 2007, Schering/Warrick immediately provided DOJ with the requested information – now more than two years ago. Had DOJ simply asked Schering/Warrick at that time – or any time before filing its opposition brief – for the "sales transaction data" that DOJ now says is so vitally important to its assessment of the settlement for the "22 additional Warrick generic drugs" and/or the Schering brand drugs, Schering/Warrick would have gladly given DOJ that data as well. In fact, simultaneously with the filing of this brief, Schering/Warrick are providing the requested information to DOJ. By the September 25 hearing, DOJ will have had the requested data for a full three weeks and should be in a position to inform the Court as to whether the data gives rise to sufficient concerns such that DOJ will intervene in this case.

The Relator has also worked diligently for years to provide the United States with all of the information that it has requested. As Mark Jones plainly states in his Declaration, uncontested by DOJ, "Ven-A-Care took action to inform DOJ, at times before November 2008, about spreads and pricing information on *all* of the drugs that are the subject of the settlement, including the Schering-brand drugs that were recently added to the Amended Complaint." (Decl. of T. Mark Jones, R.N., ¶ 9 (emphasis in original) [Dkt. 6363].) By amending the Complaint, Ven-A-Care did nothing more than conform its pleading to the evidence that it has been supplying to DOJ for years. Thus, after eleven years of litigation with Schering/Warrick and numerous DOJ requests for information to Schering/Warrick and the Relator, only DOJ is to blame if it "never fully investigated" the "recently added" drugs.[11]

[11] Presumably, DOJ could also have asked its state law enforcement partners, on whom it purports to prefer to rely for its recovery, for the very same information. Schering/Warrick have produced all of the materials that DOJ seeks to each of the litigating states as well.

DOJ's complaint that the Proposed Settlement would release conduct after 2003, (*see* DOJ Mem. 11), similarly rings hollow, particularly in light of this Court's partial summary judgment ruling in defendants favor that, after the passage of the Medicare Prescription Drug Improvement and Modernization Act (the "MMA") on December 8, 2003, "[t]he statute and legislative history indicate that [AWP] had become a term of art" and "Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace." *See In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp.2d 277, 288 (D. Mass. 2006). Similarly, DOJ's concern that Schering's spreads begin to grow starting in 2003, (*see* DOJ Mem. 11), is unfounded. As this Court well knows, "spreads" industry-wide began to grow in 2002 solely as a result of the FDB/McKesson conspiracy. *See generally* Order and Final Judgment, *New England Carpenters Health Benefits Fund* v. *First Databank, Inc.*, No. 05-11148 (D. Mass. Aug. 31, 2008) [Dkt. 829]. Schering/Warrick's February 2008 presentation to DOJ showed the precise date on which the FDB/McKesson "5% AWP bump" took effect for each Schering-brand drug. (*See* Settlement Agreement Ex. A (attached as Ex. A to Parties' Jt. Mot. For a Scheduling Conference (June 26, 2009) [Dkt. 6173-2]).)

C. The $55 Million Settlement Amount Is Commensurate with the Scope of the Release and Is "Fair, Adequate, and Reasonable Under All the Circumstances."

DOJ's final objection – that the portion of the settlement proceeds that it will receive is not commensurate with the scope of the release contemplated by the settlement – is equally without merit. As explained in the Settling Parties' Joint Memorandum, the proposed dismissal order contemplates a two-step approach: First, the Court should evaluate whether – in the aggregate – the $55 million amount is fair, adequate, and reasonable in light of the contemplated scope of the release. Second, the proposed order dismissing Schering/Warrick from the case contemplates that the Court might retain jurisdiction after Schering and Warrick are dismissed

"to determine how the settlement proceeds should be allocated in accordance with 31 U.S.C. § 3730 and other applicable law." (*See* Proposed Order Approving Settlement and Dismissal with Prejudice ¶¶ 8-9 [Dkt. 6173-2].) As Schering/Warrick demonstrate in the following section, and through the Affidavit of Paul Charnetzki (submitted herewith), a settlement payment of between $26.2 million and $32.1 million is fair, adequate, and reasonable compensation to the United States for a complete release of the federal share of any alleged Medicaid overpayment nationwide.

The fairness, adequacy, and reasonableness of the proposed settlement to the United States should be evaluated with two basic principles in mind. First, if forced to litigate its brand drug claims before this Court, DOJ could not hope to recover any damages from Schering/Warrick. As noted above, DOJ does not contest that Schering's brand drugs meet this Court's MDL liability standards. It is fundamentally unfair for DOJ to "sit on the sidelines" and seek recovery for brand drug claims that it could not bring itself by enabling states to seek the federal share of these alleged damages in state court proceedings. The fairness of the settlement must be evaluated in light of this reality. Second, as this Court pointed out during the July 24, 2009 hearing concerning this Proposed Settlement, if the settlement is not approved and Ven-A-Care simply walks away from this litigation, the United States' recovery will be limited to any amounts that it might receive through the pending state court AWP cases. (*See* 7/24/09 Hrg. Tr. 47:7-11.) Without the relator's claims, the statute of limitations has run on any viable AWP claim that the United States might bring directly against Schering/Warrick.

1. DOJ Could Not Reasonably Expect to Recover More than $32.1 Million in Damages for the Federal Share from the State Actions.

In its preliminary objections to the Proposed Settlement, DOJ actually expressed a preference to "decline to intervene" in this case, and instead recover the federal share of any

alleged Medicaid overpayment through the separate actions brought by certain states in state court "presumably pursuing both the federal and state shares of their respective state Medicaid damages." (*See* Corrected United States' Objections to the Proposed Settlement, ¶ 2 (p. 6) [Dkt. 6283].) Putting aside for this purpose all issues of knowledge, reliance, and causation and assuming that DOJ (or the states) could prevail on its claims, a straightforward analysis using CMS reimbursement data and a few simple, transparent, and reviewable assumptions with which this Court is undoubtedly familiar shows that the United States could reasonably expect to recover, if at all, between $26.2 million and $32.1 million through the pending state court cases.

As this Court is well aware, by federal statute, state Medicaid programs must set their reimbursement rates to ensure that they "are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. §1396a(a)(30)(A). Moreover, as this Court heard recently in the context of the FUL summary judgment motion in the New York counties case, in 2005, both the Government Accountability Office ("GAO") and the Department of Health and Human Services, Office of the Inspector General ("OIG") studied precisely what this access requirement means, in practice, when setting Federal Upper Limits ("FULs") for the generic drugs that are most commonly reimbursed by the Medicaid program.[12] OIG, for instance, found that, for 19 out of the top 25 reimbursed Medicaid drugs, a FUL set at 250% of the lowest reported AMP would be less than the average pharmacy acquisition cost. *See generally* Dep't of Health & Human Servs., Office of Inspector Gen., *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program* 10 (June 2007) (OEI-03-06-

[12] *See generally* Dep't of Health & Human Servs., Office of Inspector Gen., *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program* 10 (June 2007) (OEI-03-06-00400), *available at* http://www.oig.hhs.gov/oei/reports/oei-03-06-00400.pdf; Gov't Accountability Office, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs* (Dec. 22, 2006) (GAO-07-239R), *available at* http://www.gao.gov/new.items/d07239r.pdf.

00400), *available at* http://www.oig.hhs.gov/oei/ reports/oei-03-06-00400.pdf. Accordingly, Schering/Warrick asked Mr. Charnetzki to model the difference between the ingredient cost reimbursement paid by each litigating state for each of the Warrick-generic drugs on which the state has sued and the amount that the state would have reimbursed for ingredient costs had the state only reimbursed at 250% of Warrick's AMP. This basis, Schering/Warrick submit, results in an over-estimate of damages – because the "but for" reimbursement rate being assumed – in many cases – would not even be sufficient to cover a pharmacy's acquisition cost for that drug. For purposes of this Court's evaluation of the fairness, adequacy, and reasonableness of the settlement, however, Schering/Warrick submit this measure of damages supplies the Court with a conservative benchmark. Measured in this manner, the federal share that the United States could reasonably expect to recover is $32.1 million.

The Court might also recall from the FUL summary judgment briefing that, based in significant part on the OIG and GAO reports referenced above, CMS was enjoined from setting FULs on the basis of 250% of AMP, *see* Order of December 17, 2007, *Nat'l Ass'n of Chain Drug Stores* v. *U.S. Dep't of Health & Human Servs.*, No. 07-cv-02017-RCL (D.D.C. Nov. 7, 2007) [Dkt. 36], and that Congress is now considering mandating that FULs be set based on 300% of the weighted average of AMPs for the class of drugs to more adequately ensure access. *See* Senate Finance Committee, Description of Policy Options, *Expanding Health Care Coverage: Proposals to Provide Affordable Coverage to All Americans*, at 27 (May 14, 2009), *available at* http://finance.senate.gov/sitepages/legislation.htm (select "5-11-09 Baucus, Grassley Policy Options" hyperlink listed under "May 2009" heading). Using this 300% of AMP

assumption as the basis for the "but for" world values the federal share at approximately $26.2 million.[13]

As this analysis demonstrates, $55 million is a fair, adequate, and reasonable amount for Schering/Warrick to pay to resolve its possible liability for the federal share of any alleged Medicaid overpayment nationwide and the state shares in California and Florida to which no objections have been raised. The $55 million amount is more than sufficient to cover what the United States can reasonably expect to recover through the pending state actions, and there should be sufficient amounts remaining to adequately compensate California and Florida, and the Relator for its statutory share. In any event, as noted at the outset, allocation of the $55 million settlement amount is a second step in the process that the Court need reach only after concluding that, in total, $55 million is fair, adequate, and reasonable and dismissing Schering and Warrick from this case with prejudice.

Schering/Warrick can imagine a number of other perspectives from which to evaluate the fairness, adequacy, and reasonableness of the settlement. In each of these scenarios, the likely damages award would have to be discounted to account for the litigation risks inherent in pursuing a case through trial. As the Settling Parties point out in their Joint Memorandum, there are significant litigation risks inherent in pursuing an AWP case through trial. (*See* Jt. Mem. 19-

[13] The only other assumption reflected in Mr. Charnetzki's calculations is the assumption that, once CMS decided to set a FUL for a particular NDC, there cannot be future damages for that NDC. As the Court heard (and apparently accepted) in the FUL summary judgment context, CMS's decision to set or remove a FUL, and at what level, was the result of a highly discretionary process. *See* 7/8/09 Hrg. Tr. 28:4-5 (THE COURT: "Well, we know they're [referring to CMS] flat out violating this regulation."); *id.* 52:6-7 (THE COURT: "[T]he agency did not follow its own regulation in many instances.").) This assumption about future damages reflects nothing more than the simple fact that Schering/Warrick should not be held responsible for CMS's discretion once CMS identified the drug as a candidate for a FUL.

23.) Moreover, as this Court knows, defendants rarely pay 100% of the alleged damages to settle a case.[14]

2. DOJ's Approach to Calculating Damages is Fundamentally Flawed, Irresponsible, and Should Not Be Accorded Any Weight.

DOJ's approach to "evaluating" (if it can be called that) the adequacy of the proposed settlement payment is so elementary and fundamentally flawed that it is irresponsible. All DOJ does, without any expert support, is sum up the total CMS reimbursement paid (it is not clear that DOJ even backs out dispensing fees) for all Warrick-generic drugs over the time period 1993 to 2003, and concludes that the portion of the settlement proceeds that it expects to receive is small by comparison. This comparison, however, fails to take into account such basic matters as a pharmacy's acquisition cost and Medicaid's statutory access requirement. It stands to reason that pharmacies do not obtain the drugs that they dispense for free. DOJ's "damages model" (again, if it can be called that) fails to account for any of this. No basis is offered for using total utilization as a relevant foundation for calculating possible damages, nor could such a basis be supported on the record before this Court.

The carelessness with which DOJ banters about the "spread" findings from the MDL, as if they somehow might absolve DOJ from its obligation to seriously consider the $55 million settlement being proposed, is equally troubling. As this Court well knows, having heard it time and again during the MDL bench trial, even "mega-spreads" on generic drugs costing only pennies, in absolute dollar terms, do not give rise to "mega" damages. *See In re Pharm. Indus.*

[14] For example, in the GSK settlement of the MDL Class Action which this Court approved as fair, adequate, and reasonable on August 7, 2007, GSK settled class claims nationwide for only 12.6 % of the damages that had been calculated by Plaintiffs' expert Dr. Hartman. (*Compare* Supp. Decl. of Raymond S. Hartman in Support of Pls.' Claims of Liability and Calculations of Damages: Addendum at 2, Table 1 (Feb. 3, 2006) (calculating total class nationwide nominal damages for GSK of $519,874,714) *with* Settlement Agreement and Release of the GlaxoSmithKline Defendants ¶ 3(a) (Aug. 10, 2006) [Dkt. 2972] (providing that GSK would pay $65.5 million for a full and final release of all pending class claims).)

Wholesale Price Litig., 520 F. Supp. 2d 267, 271 (D. Mass. 2007) (finding spreads on Warrick's albuterol caused no damages). The proposed $55 million settlement is fair, adequate, and reasonable, and commensurate with the scope of the release sought, and none of DOJ's stated reasons to the contrary offers a sufficient ground in law or fact for the Court to conclude otherwise.[15]

III. THE ARGUMENTS MADE BY THE OBJECTING PARTIES ARE INCONSEQUENTIAL.

The Objecting Parties oppose the settlement because it is designed *inter alia* to restrict the scope of damages they seek in the state court actions. (*See* Amicus Curiae of the States of Wisconsin, Alaska, Idaho, Illinois, Kentucky, and Mississippi 1-2 (Aug. 21, 2009) [Ven-A-Care Sub-Dkt. 377] (the "Wisconsin Amicus Brief"); Commonwealth of Massachusetts Opp. To Jt. Mot. For Approval of Settlement Between California, Florida, and Ven-A-Care and the Schering Defs. 4-6 (Aug. 30 2009) [Dkt. 6457] (the "Massachusetts Amicus Brief"); City of New York and New York Counties' Response and Objection to the Motion to Approve the Proposed Settlement Between California, Florida and Relator Ven-A-Care of the Florida Keys On Behalf of Itself and the United States and Schering-Plough, Schering & Warrick 2-3 (Aug. 28, 2009) [Dkt. No. 6435] (the "New York Counties Amicus Brief").) The Objecting Parties acknowledge, however, that the proposed settlement reaches only the federal share of any damages sought by

[15] To the extent that it is even relevant, Massachusetts's evaluation of the fairness, adequacy, and reasonableness of this settlement is premised on Massachusetts's own outsized damages calculation. The approximately $12 million damages number that Massachusetts references represents both the federal and state shares of Massachusetts's claimed damages and the flawed assumption that WAC=AMP. *See* Hr'g Tr. on Summary Judgment 72:11-18, 73:1-6, *Commonwealth of Massachusetts* v. *Mylan Labs., Inc.*, No. 03-cv-11865 (D. Mass. June 18, 2008) (hereinafter, *Massachusetts* v. *Mylan*) (rejecting argument that WAC=AMP). When corrected to recognize Massachusetts Medicaid's statutory obligation to ensure adequate access, and when limited to the state share, Massachusetts's alleged damages fall roughly within 3-5% of the national total range that Massachusetts suggests they should. Moreover, verdicts against other companies involving different drugs are simply irrelevant to the fairness, adequacy, and reasonable of this settlement. (*See* 7/17/07 Status Conf. Tr. 20, *Commonwealth of Massachusetts* v. *Mylan* ("the one thing I learned from the other [AWP] case is, this is resolved company by company, drug by drug, NDC by NDC, and quarter by quarter."). In short, the arguments advanced by Massachusetts add nothing to this Court's analysis of the fairness, adequacy, and reasonableness of this settlement.

the states. (Wisconsin Amicus Br. 2; Massachusetts Amicus Br. 1.) The rights of the states are not compromised simply because the rights of the United States are resolved by the settlement.

A. This Settlement Would Have Preclusive Effect As to the Federal Share of Any Alleged Damages Even in the Wake of the DRA.

That the Deficit Reduction Act of 2005 ("DRA"), as an incentive to states to recover overpayments on behalf of the federal government, permits states who recover money under state false claims acts for Medicaid overpayment to retain a percentage of the federal share, (*see* Massachusetts Amicus Br. at 5), does not give states such as Massachusetts the right to proceed with claims for the federal share where such claims have already been resolved in a federal FCA action. Rather, the DRA provision is only triggered where the state is obligated to pay the Federal Medical Assistance Percentage ("FMAP") of its recovery to the federal government. *See* 42 U.S.C. § 1396h(a). Where, as here, claims for the federal share will have been resolved and released, the state need not pay an FMAP-based portion of its recovery for the state share to the federal government, and Section 1396h(a) is therefore inapplicable.

In effect, this is a "classic" situation where two cases are filed seeking the exact same dollars – the federal share of the alleged overpayment. To avoid double recovery, resolution of the claims in the first case ***must*** preclude continued action that seeks the same dollars in the second case. *See Giragosian* v. *Ryan*, 547 F.3d 59, 65 (1st Cir. 2008) ("[W]hen two actions are pending which are based on the same claim, or which involve the same issue, it is the final judgment first rendered in one of the actions which becomes conclusive in the other action . . ., regardless of which action was first brought.") (citing Restatement (Second) of Judgments § 14, cmt. a (1982)). Though the Objecting Parties assert generally that the settlement would not extinguish their claims as to the federal share, (*see* Massachusetts Amicus Br. at 5-6), they fail to

rebut Schering/Warrick's legal argument that the release embodied in the Proposed Order would have preclusive effect on any claim for the federal share. (Jt. Mem. 16-18.)

B. The Objecting Parties' Objections to the Proposed Findings are Unfounded and Merely Underscore the Need to Resolve Claims for the Federal Share in Federal Court.

Pressing further, the Objecting Parties object to the proposed findings of fact, asserting that the facts should be adjudicated in various state courts. (Wisconsin Amicus Brief 5.) Of course, nothing in the settlement purports to affect the rights of states to adjudicate the facts relating to their claims for damages to the state in state courts. Similarly, the Objecting Parties express concern that the findings of fact may "influence state courts and sway jurors." (Wisconsin Amicus Br. 3.) This is hardly a serious basis for objection to the settlement. Indeed, the Objecting Parties have been swift to present any decisions of this Court that they find useful in their own proceedings. *See, e.g.*, Pls.' Mot. for Leave to File Supplemental Authority, *State of Wisconsin* v. *Abbott Labs.*, Case No. 04-CV-1709 (Jan. 5, 2009)(seeking leave to file this Court's December 23, 2008 decision). If the Objecting Parties wish to litigate in the state courts, then presumably they are comfortable relying on state court judges to determine whether the findings have any persuasive value or other legal effect.

There is likewise no merit to the argument that an inadequate record exists for this Court to make the Requested Findings. (*See* New York Counties Amicus Brief 3-6.) The New York Counties Amicus Brief argues that Schering/Warrick's grievances regarding their inability to obtain testimony of federal government officials is overstated because discovery of federal officials has been taken in this MDL and is "useable for all purposes in these proceedings." (*Id.* at 8-9.)[16] By the same token, the adequacy of the record here must be judged, not merely on the

[16] As an initial matter, the paragraph of the Affidavit of Beth Trent cited to by the New York Counties expressly notes that the inability to obtain discovery of federal officials is particularly problematic in cases that are pending in

discovery taken in the actions being settled, but on the voluminous record in this MDL. The Objecting Parties have received all documents and data produced by Schering/Warrick in this MDL and every other state AWP proceeding. That record includes significant discovery relating to brand drugs, both as part of the MDL class case and as part of various state cases implicating brand drugs. The MDL record, after nine years of litigation, is more than sufficient for the Court to enter the requested findings.

The argument that the Court should not make the requested findings because they amount to nothing more than an impermissible "advisory opinion" is similarly without merit. (Wisconsin Amicus Br. 2; New York Counties Amicus Br. 2-3; Massachusetts Amicus Br. 6-8.) As the Settling Parties demonstrate in the Joint Memorandum, Article III courts are empowered to make the type of findings requested, and do so, in approving settlements all of the time. (Jt. Mem. 11-14.) Moreover, the requested findings are integral to this Court's conclusion that the settlement is fair, adequate, and reasonable. As such, findings that are integral to an ultimate (and clearly disputed) issue are simply not "advisory" as the Objecting Parties contend. *See Rhode Island* v. *Narragansett Indian Tribe*, 19 F.3d 685, 693 (1st Cir. 1994) (opinion not advisory where controversy admits of "specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts" (internal quotation marks omitted)).

The positions taken by the various Objecting Parties merely reinforce the concerns raised in the Trent Affidavit regarding the obstacles to settlement faced by Schering/Warrick and highlight the due process issues that would be created if Schering/Warrick could not resolve

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state courts around the country, not those that are part of this MDL. (*See* Affidavit of Beth Trent, ¶ 19 (Aug. 7, 2009) [Dkt. No. 6362] (the "Trent Aff.").) Of course, that other defendants have been able to take discovery of certain federal officials and that such discovery is part of the record in this MDL does little to mitigate the concerns raised in the Trent Affidavit regarding state courts – before which claims as to the federal share are being presented – refusing to admit evidence or testimony relating to the operation of Medicaid at the federal level.

liability as to the federal share in the federal actions pending against them. The Wisconsin Amicus Brief, for example, notes that Wisconsin and the other states joining that brief, seek damages on any and all drugs where the AWP did not reflect the precise average of prices paid by pharmacies for drugs. (Wisconsin Amicus Br. 3.) Thus, Wisconsin seeks to recover the federal share of an "overpayment" with respect to drugs for which the spread is nothing but a formulaic WAC to AWP mark-up.[17] Whatever the merits of the state's claims with respect to the state share, Schering/Warrick should not be deprived of a fair opportunity to litigate and resolve issues relating to the federal share in this federal *qui tam* action, particularly where they are routinely denied the opportunity, in state cases, to present evidence relating to the role of the federal government, the real party in interest with respect to the federal share. *See* Trent Aff. ¶¶ 15-21; *see also Burch ex rel. U.S.* v. *Piqua Eng'g, Inc.*, 145 F.R.D. 452, 457 (S.D. Ohio 1992) (denying defendant opportunity to "have its case heard" deprives defendant of its procedural due process rights) (citing *Logan* v. *Zimmerman Brush Co.*, 455 U.S. 422, 429 (1982)).

C. This Court Should Reject Outright the Contention that No Finality as to the Federal Share of Damages Can Be Achieved Before this Court.

Additionally, Massachusetts takes the remarkable position that, even a settlement and release joined by the United States would not extinguish state claims for the federal share, but rather, would merely constitute an offset to any damages ultimately awarded to Massachusetts with respect to the federal share. (*See* Massachusetts Amicus Br. 6.) This is yet another example

[17] To justify that position, the brief advances the type of outright misstatement that Schering/Warrick routinely face in state court cases: "It is uniformly the case that the state Medicaid programs were unaware that the published AWPs were 20% or 25% higher than the prices actually paid by pharmacies for drugs." (Wisconsin Amicus Br. 3) For at least thirty years, HCFA and then CMS have told state Medicaid programs that AWP did not represent a market price and exceeded the acquisition cost of pharmacies. *E.g.* WI-Prod-AWP-108021-24 (document produced from Wisconsin's files analyzing 1996 OIG report finding that pharmacies acquire brand drugs for an average price of AWP minus 18.3 % and HCFA's instructions to the state that HCFA "historically provided guidance to the states that AWP is not an accurate estimate of acquisition costs without a discount off AWP being applied. We therefore expect that states will consider the results of this (OIG) report as one of the factors in contemplating proposed changes to policy reimbursement.").

of the structural impediments to resolution of AWP litigation created by the untenable positions adopted by certain States concerning the federal-state nature of Medicaid reimbursement. (Trent Aff. ¶ 17.) According to Massachusetts, Schering/Warrick is powerless to fix its liability for the federal share of any alleged overpayment. Even if the United States directly released claims for the federal share – or, indeed, even if a judgment entered in favor of the United States after trial – according to Massachusetts, it could press on and continue to seek a recovery for the federal share in excess of the amount the federal government deemed a reasonable compromise or the amount awarded by a court/jury. No Defendant could justify paying significant sums in any settlement for the federal share that leaves its exposure for damages with respect to federal share of any alleged overpayment so completely open-ended and uncertain.

CONCLUSION

For all of the foregoing reasons, the Settling Parties respectfully request that this Court (i) proceed to evaluate the fairness, adequacy, and reasonableness of their proposed settlement sequentially, as outlined above; (ii) enter the requested the findings of fact; (iii) consent to the Settlement in writing clearly stating its reasons for consenting; (iv) after making its own determinations, request that the United States indicate whether it will consent to the dismissal and, if not, require that it specify its reasons; and (v) evaluate those stated reasons and ultimately

approve the proposed settlement and enter an appropriate order dismissing these actions with prejudice as requested in the Settlement.

Respectfully submitted,

/s/ John P. Bueker
John T. Montgomery
John P. Bueker
Ropes & Gray LLP.
One International Place
Boston, MA 02110-2624
(617) 951-7000

John P. McDonald
Locke Lord Bissell & Liddell
2200 Ross Avenue, Suite 2200
Dallas, TX 75201

Attorneys for Schering Corporation,
Schering-Plough Corporation and
Warrick Pharmaceuticals Corporation

Dated: September 4, 2009

CERTIFICATE OF SERVICE

I hereby certify that on September 4, 2009, a true copy of the above Joint Motion was served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

September 4, 2009

/s/ John P. Bueker
John P. Bueker